FDA Lifts Clinical Hold on BMF-219 in Type 2 and Type 1 Diabetes Trials

September 26, 2024

REDWOOD CITY, Calif., Sept. 26, 2024 (GLOBE NEWSWIRE) -- Biomea Fusion, Inc. (“Biomea” or the “Company”) (Nasdaq: BMEA), a clinical-stage biopharmaceutical company dedicated to discovering and developing oral covalent small molecules to treat and improve the lives of patients with metabolic diseases and genetically defined cancers, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on Biomea’s ongoing Phase I/II clinical trials of the Company’s investigational covalent menin inhibitor BMF-219 in type 2 and type 1 diabetes (COVALENT-111 and COVALENT-112), respectively.

“We greatly appreciate FDA’s review of our data, and the swift resolution of the clinical trial hold. The in-depth review of the clinical data to date reconfirms our confidence in BMF-219 as a novel, first-in-class agent for the treatment of diabetes. We are encouraged from the safety review of the ongoing Phase 2b Expansion Study, where the concerning safety signals seen in the Phase 2a Escalation Study did not translate over to the larger Expansion Study. And most importantly, none of the elevated lab values translated to confirmed serious liver injury or liver impairment,” stated Thomas Butler, Biomea Fusion’s Chief Executive Officer and Chairman of the Board. “We look forward to continuing our robust development plan for BMF-219 following full resumption of our ongoing studies, COVALENT-111 and COVALENT-112.”

Conference Call and Webcast Details

Webcast of Biomea’s investor update today, Thursday, September 26 th at 4:30 pm ET will be available to registered attendees under the Investors and Media section of the company’s website at https://investors.biomeafusion.com/news-events/events.
A replay of the presentation will be archived on Biomea’s website following the event.

Diabetes Milestones for Q4 2024

- Announce a third development candidate, a potent, selective, oral small molecule GLP-1 receptor agonist
- Topline Week 26 data readout of Phase 2b with approximately 200 patients of COVALENT-111
- Topline data readout of Phase 2a of COVALENT-112 with approximately 20 patients

About COVALENT-111

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy patients were enrolled in single ascending dose cohorts to evaluate safety at the prospective dosing levels for type 2 diabetic patients. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by standard of care medicines. Once the Escalation Phase of COVALENT-111 was completed, the study advanced into an Expansion Phase (Ph IIb) consisting of multiple cohorts dosing type 2 diabetes patients for longer dose durations. Additional information about this Phase I/II clinical trial of BMF-219 in type 2 diabetes can be found at ClinicalTrials.gov using the identifier NCT05731544.

About COVALENT-112

COVALENT-112 is a multi-site, randomized, double-blind, placebo-controlled Phase II study in adults with stage 3 type 1 diabetes. This stage describes the period following clinical diagnosis of type 1 diabetes when symptoms are present due to significant beta cell loss. COVALENT-112 will be a multi-arm trial comparing two different doses of BMF-219 to placebo (1:1:1) to evaluate the efficacy, safety, and durability of BMF-219 in adults with type 1 diabetes. Approximately 150 patients will be enrolled in the trial and will receive either BMF-219 or placebo over 12 weeks, followed by a 40-week off treatment period.

This trial also includes an open-label portion for adults with type 1 diabetes up to 15 years since diagnosis. The open-label portion (n=40) is examining the efficacy, safety, and durability of BMF-219 at two oral dose levels, 100 mg and 200 mg over 12-week treatment followed by a 40-week off treatment period.

Additional information about the Phase II clinical trial of BMF-219 in type 1 diabetes can be found at ClinicalTrials.gov using the identifier NCT06152042.

About Biomea Fusion
Biomea Fusion is a clinical stage biopharmaceutical company focused on the discovery and development of oral covalent small molecules to treat patients with metabolic diseases and genetically defined cancers. A covalent small molecule is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional non-covalent drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response.

We are utilizing our proprietary FUSION™ System to discover, design and develop a pipeline of next-generation covalent-binding small molecule medicines designed to maximize clinical benefit for patients. We aim to have an outsized impact on the treatment of disease for the patients we serve.

We aim to cure.

Visit us at biomeafusion.com and follow us on LinkedIn, Twitter and Facebook.

Forward-Looking Statements

Statements we make in this press release may include statements which are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will,” and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding the clinical and therapeutic potential of our product candidates and development programs, including BMF-219, the potential of BMF-219 as a treatment for type 2 and type 1 diabetes, our research, development and regulatory plans, the progress of our ongoing and planned clinical trials, including COVALENT-111 and COVALENT 112, , the availability of data from our clinical trials and the timing of such events, may be deemed to be forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including the risk that we may encounter delays in preclinical or clinical development, patient enrollment and in the initiation, conduct and completion of our ongoing and planned clinical trials and other research and development activities. These risks concerning Biomea Fusion’s business and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission (the “SEC”), including its most recent periodic report filed with the SEC and subsequent filings thereafter. Biomea Fusion explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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